Exhibit I

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An oscillating/pulsating electric toothbrush versus a high-frequency electric toothbrush in the treatment of gingivitis

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KEYWORDS
Oscillating/pulsating electric toothbrush;
High-frequency electric toothbrush;
Plaque;
Gingivitis;
Gingival abrasion

Summary *Objectives.* The objective of this study was to compare the effect of an oscillating/pulsating power toothbrush (Oral-B ProfessionalCare™ 7000; PC 7000) and a high-frequency power toothbrush (Philips Sonicare® Elite®; SE) on the reversal of experimental gingivitis.
Methods. The study had a randomised, examiner-blind, split-mouth design. After dental prophylaxis, subjects refrained from brushing mandibular teeth for 21 days to allow development of gingivitis. During a 4-week treatment phase, the right or left side of the mouth was brushed with either the PC 7000 or the SE toothbrush as randomly allocated. Plaque and gingivitis were assessed at baseline (Day 0), after 21 days of no oral hygiene, and after 1, 2 and 4 weeks of brushing twice daily. Gingival abrasion was assessed at Day 0 and after 1, 2 and 4 weeks of product use.
Results. Of 38 enrolled subjects, 35 provided evaluable data. The experimentally induced gingivitis (EIG) phase resulted in higher bleeding and plaque scores as compared to Day 0. During the treatment phase, plaque and bleeding scores were significantly lower with the PC 7000 than the SE toothbrush. After 4 weeks of use, the mean plaque scores changed from 2.78 (Day 21 of EIG phase) to 0.70 for the PC 7000 and from 2.67 (Day 21) to 0.88 for the SE. The mean bleeding scores changed from 1.86 (Day 21) to 1.24 for the PC 7000 and from 1.88 (Day 21) to 1.42 for the SE. No major differences were found between brushes with regard to gingival abrasion.
Conclusions. The oscillating/pulsating power toothbrush (Oral-B ProfessionalCare 7000) was more effective than the high-frequency power toothbrush (Philips Sonicare Elite) at plaque removal and improvement of gingival condition, with no greater potential for causing gingival abrasion.

Introduction

A regular daily programme of oral hygiene is vital for the maintenance of oral health. Unimpeded accumulation of plaque bacteria rapidly gives rise to the development of gingivitis, clinically manifested as gingival redness, swelling and an increased propensity to bleeding[1,2]. Attempts to disrupt plaque mechanically, usually by manual toothbrushing, often fail to achieve optimal gingival health[3,4]. Ineffective plaque control by toothbrushing

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can result from poor technique, insufficient duration of use, irregular performance, and lack of motivation.

One approach to enhance the brushing technique and encourage compliance has been the development of the electric toothbrush. Toothbrushes with small round brush heads and oscillating/rotating action have consistently shown to be highly effective in both plaque removal and control of gingivitis, without compromising safety to oral tissues[5-7]. Indeed two recent independent systematic reviews, one undertaken by the Cochrane Collaboration, confirmed that oscillating/rotating toothbrushes have superior efficacy over manual toothbrushes in reducing plaque and gingivitis[8,9]. Continual research to improve further the cleaning efficiency of power toothbrushes has resulted in the addition of a pulsating action in the Oral-B ProfessionalCare™ Series, which have three-dimensional movement to the brush head with greater access to approximal sites[10], a known focus for plaque accumulation and gingivitis[11,12].

The most recent model to be introduced is the Oral-B ProfessionalCare 7000 (PC 7000; Oral-B Laboratories, Boston, MA, USA), which compared to its predecessor, the 3D Excel, has an increased oscillating frequency from 63 Hz to 73 Hz but the same pulsating frequency of 340 Hz. Incorporation of a pressure control system into these models limits brushing force and thereby reduces the possibility of trauma to oral tissues during use.

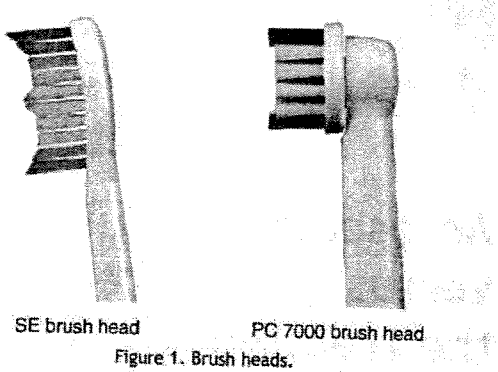
Another electric toothbrush based on a different technology is the Sonicare® Elite® (SE; Philips Oral Healthcare, Snoqualmie, WA, USA), which has an oval-shaped brush head where the filaments vibrate in a side-to-side motion with a frequency of 260 Hz[13]. Some studies have shown that the Sonicare has greater plaque removal ability than a manual toothbrush while its effect on gingival inflammation is similar to manual brushing[14-16].

As new models are developed it is important to evaluate their safety and relative ability to remove plaque and improve gingival health so dental professionals are informed about the most effective toothbrushes available. The primary objective of the present study was to compare the PC 7000 and the SE in their relative ability to improve gingival condition using an experimental gingivitis model[17], where subjects refrained from oral hygiene for 21 days to allow development of gingivitis before commencement of treatment. A secondary objective was to evaluate the relative potential of the two power toothbrushes to cause gingival abrasion. The study had three phases: the familiarisation phase (so that subjects became acquainted with the use of both power toothbrushes), the experimental gingivitis phase (no oral hygiene for 21 days in the lower jaw so that a reasonable level of gingivitis developed, i.e., 40% bleeding on marginal probing)[2,18,19], and the treatment phase (for assessment of the effect of the toothbrushes on gingival condition).

Material and Methods

Toothbrush design

The PC 7000 brush head has an oscillating/rotating/pulsating motion with an oscillating frequency of 73 Hz and an oscillation angle of 45°. The pulsating motion has a frequency of 340 Hz. The brush has a pressure control system that limits brushing force by switching off the vibratory action at a preset pressure. The brush head has a diameter of 13.2 mm with individual filaments of 0.006 inches (0.1524 mm) in diameter. The SE operates with a side-to-side bristle action at a frequency of 260 Hz and has a brush head with a curved side profile and a neck slightly angled relative to the handle (Fig. 1). The easy-start feature was deactivated prior to use as recommended by the manufacturer. All subjects were instructed to use the SE and PC 7000 in preset high-speed mode.



SE brush head PC 7000 brush head

Figure 1. Brush heads.

Subjects

Thirty-eight healthy subjects of both sexes were recruited from a population of university students. The volunteers were informed of the study, first in a recruitment letter and then secondly at the first appointment. They were given a written explanation of the background of the study, its objectives and their involvement. After screening for their suitability they were all requested to give their written informed consent. They were required to fulfil the following inclusion criteria: non-smokers; a minimum of 5 evaluable teeth in each quadrant in the lower jaw (with no partial dentures, orthodontic banding or wires); an absence of oral lesions and/or periodontal pockets >5 mm; and a level of gingival bleeding more than 25%. Dental students, dental professionals and subjects using an oscillating/rotating toothbrush or a high-frequency toothbrush at home were excluded from the study. The study was approved by the Medical Ethical Committee of the Academic Medical Centre (AMC) of Amsterdam (Approval #: MEC 03/180 # 03.17.1021).

Study design

The study had a three-phase, randomised, examiner-blind, split-mouth design. Two weeks before study commencement (Fig. 2), subjects were given brief verbal instruction in the use of both the PC 7000 and the SE toothbrushes and written instructions were provided. Each subject received a box of wood sticks (Oral-B extra fine, Oral-B Laboratories, Boston, MA, USA) for interdental cleaning and written instructions for their usage. Subjects were instructed to use the wood sticks

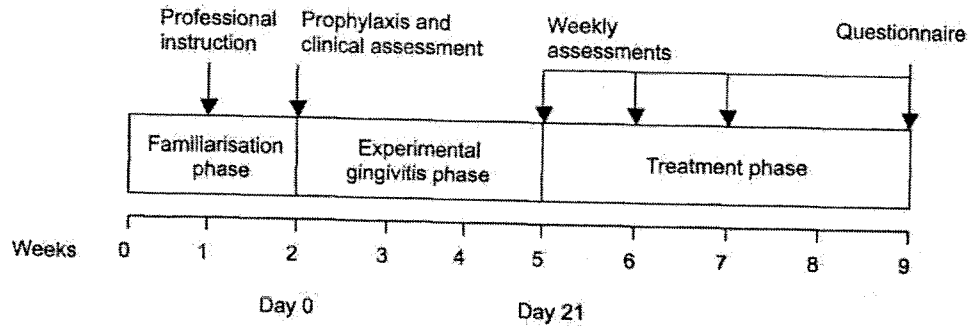


Figure 2. Study design.

once daily at all sites and brush twice daily for two minutes with a standard toothpaste (Zendium Classic, RDA ± 76; Sara Lee DE International b.v., Utrecht, The Netherlands), using the toothbrushes on alternate days, and recorded brushing times on a brush calendar.

One week later, subjects received professional instruction in the use of the two electric toothbrushes and the wood sticks, and were given a new brush calendar. After a further week, subjects returned for the first assessment (Day 0) of gingivitis, plaque and gingival abrasion in the lower jaw. Gingival condition was assessed using the bleeding on marginal probing (BOMP) index, where the gingival margin was probed at an angle of approximately 60° to the longitudinal axis of the tooth and the absence or presence of bleeding was scored within 30 seconds of probing on a scale 0-2 (0 = non-bleeding, 1 = pinprick bleeding, 2 = excess bleeding)[2,18,19]. Then the lower jaw was disclosed using a new cotton swab with fresh disclosing solution for each quadrant (Mira-2-Ton®; Hager & Werken GmbH & Co. KG, Duisburg, Germany). After disclosing, plaque was assessed using the Turesky et al. modification[20] of the Quigley & Hein index[21] scored at six sites per tooth as suggested by Lobene et al.[22], where the absence or presence of plaque was recorded on a scale 0-5 (0 = no plaque, 5 = plaque covering more than two-thirds of the tooth surface). Third molars and central incisors were not assessed to avoid the effect of overlapping adjacent quadrants during brushing. The gums were also disclosed using Mira-2-Ton disclosing solution for better visualisation of the number and site location of any gingival abrasions (third molars and central incisor regions were excluded). The gingival tissues were divided into three areas: marginal (cervical free gingiva), approximal (papillary free gingiva) and mid-gingival (attached gingiva) (Fig. 3). A PQ-Williams periodontal probe, placed across the long axis of the lesions, was used to measure the size of the abrasions and the greatest diameter of the lesion was recorded. The lesions were assessed as small (≤2 mm), medium (≥3 but <5 mm) or large (≥5 mm), with those between 2 and 3 mm assigned as small or medium according to the nearest mm mark on the probe[23-26].

Subjects then received a dental prophylaxis so they entered the experimentally induced gingivitis (EIG) phase with equally clean teeth. They were instructed to refrain

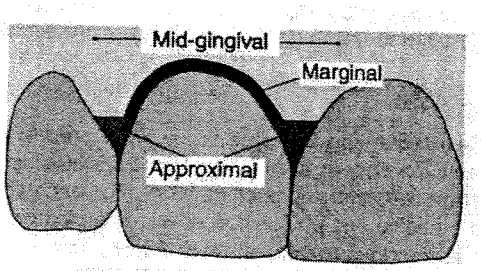


Figure 3. Location of gingival abrasion.

from brushing mandibular teeth for 21 days, during which time they brushed, for further familiarisation, their upper jaw on alternate days with one of the two brushes. Use of mouth rinses, dental floss or wood sticks was prohibited. After 21 days, subjects were scored for gingival bleeding and plaque in the lower jaw, and those with at least 40% of bleeding in each quadrant entered the treatment phase of the study.

All subjects received a new brush head for each brush handle and a new brush calendar. During the 4-week treatment phase, subjects were instructed to brush their teeth with the supplied standard toothpaste according to a split-mouth design, whereby the right or left side of the mouth was brushed for a period of 1 minute per side with either the PC 7000 or SE, as randomly allocated. To ensure that subjects brushed the correct quadrant with the correct brush, a reminder photo sticker was provided for the bathroom mirror. A timer was provided to allow measurement of the 30-second brushing period per quadrant. Use of other oral hygiene measures such as mouth rinses, dental floss or wood sticks during this phase of the study was forbidden. Subjects were instructed to brush between 2 and 3 hours before each clinic appointment to avoid the risk of increased bleeding as a result of toothbrushing[27]. After 1, 2 and 4 weeks, subjects were reassessed for gingival bleeding, plaque and gingival abrasion.

Throughout the study all examinations were performed by the same examiner (MP) under the same conditions. The examiner was blind to treatment randomisation and records of earlier examinations were not available at the time of re-examination. At the end of the study, all subjects completed a questionnaire designed to evaluate their preferences for and attitudes towards the two toothbrushes used.

Table 1 Overall plaque and bleeding scores (mean±SD)

(n = 35)		Experimental gingivitis phase		Treatment phase		
		Day 0	Day 21 (baseline gingivitis)	Week 1	Week 2	Week 4
Plaque*	PC 7000	0.82±0.44	2.78±0.51	0.70±0.39	0.55±0.38	0.70±0.44
	SE	0.78±0.44	2.67±0.57	0.91±0.50	0.76±0.45	0.88±0.44
			$P = 0.0468$	$P = 0.0259$	$P = 0.0096$	$P = 0.0323$
Bleeding**	PC 7000	0.94±0.35	1.86±0.22	1.51±0.27	1.33±0.37	1.24±0.32
	SE	1.05±0.34	1.88±0.21	1.68±0.24	1.54±0.23	1.42±0.27
			$P = 0.1826$	$P = 0.0002$	P<0.0001	$P = 0.0019$

Comparison between toothbrushes by ANOVA.
*Overall ANOVA (for weeks 1, 2 and 4 of treatment phase); PC 7000 *versus* SE, $p = 0.024$.
**Overall ANOVA (for weeks 1, 2 and 4 of treatment phase); PC 7000 *versus* SE, $p < 0.001$.

Data analysis

For the plaque and bleeding scores, the present design was able to discern a difference of 0.25 at a standard deviation 0.40 and a power of >80%. For each subject, mean bleeding and plaque scores were calculated for all sites, all vestibular sites, all lingual sites, mid-vestibular sites, mid-lingual sites, approximal vestibular sites and approximal lingual sites. Comparison between brushes for both plaque and bleeding indices was performed using an overall repeated measures analysis (ANOVA) with measurements at 1, 2, and 4 weeks as the dependent variables and scores on both Days 0 and 21 as covariates. Residuals analyses were performed to confirm validity of the calculated p-values. Explorative analysis was performed to determine the location (site in the mouth) and tooth type (i.e. front, premolar, molar) where differences in plaque and bleeding scores occurred between toothbrushes using Wilcoxon tests. Original p-values were reported for the proper interpretation of the effects and the influence of overall tests as applied to primary response variables. The mean number of gingival abrasion sites was calculated by gingival region and sorted by size. Gingival abrasion data were analysed using Wilcoxon tests to compare scores for both brushes at each assessment. An explorative analysis of scores for the size categories (small, medium, large) was performed. Data from the questionnaire were analysed using a Wilcoxon test for the visual analogue scale (VAS) scores and a binomial test for questions with binomial choices. Values of $p < 0.05$ were considered as statistically significant.

Results

Subject population

Thirty-eight subjects were recruited. One subject did not show up for the first appointment and therefore 37 subjects were enrolled into the study. Thirty-five subjects completed the protocol; 2 withdrew for reasons unrelated to the study. The evaluable subject sample comprised 8 males and 27 females with a mean age of 23.7 years (range, 19–44 years). All subjects had good general health and were not taking any medication that could interfere with the study outcomes. According to the returned brush calendars, compliance of the twice-daily brushing regimen during the 4-week treatment phase was almost 100% for all participants during the study.

Plaque

During the EIG phase (Day 0 to Day 21), the plaque index scores increased markedly and a marginally significant difference between both brushes was observed at Day 21 (Table 1). Plaque was notably reduced by the first week of treatment for both toothbrushes, but levels were consistently below the first assessment (Day 0) value throughout the treatment phase only with the PC 7000. A comparison of the two toothbrushes indicated that the PC 7000 was significantly more effective in overall plaque removal than the SE throughout the study. After 4 weeks of use, mean plaque levels reduced from 2.78 (Day 21) to 0.70 for the PC 7000 and from 2.67 (Day 21) to 0.88 for the SE (Table 1). In the analysis both covariates, Day 0 and Day 21 scores, were significantly related to the dependent variables ($p = 0.0002$, $p = 0.0341$, respectively). An explorative analysis of plaque levels by tooth type revealed no significant difference between toothbrushes in baseline scores for front, premolar or molar teeth, but during the treatment phase significantly greater reductions in plaque were evident with the PC 7000 over the SE on premolars at Week 1 and Week 4 and on front and molar teeth at Week 2 (Fig. 4). As for reductions in plaque scores on different tooth sites, advantages in favour of the PC 7000 were found especially on approximal sites (Table 2).

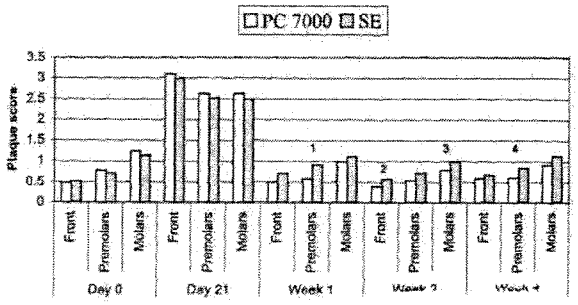


Figure 4. Plaque score by tooth type. Wilcoxon test: [1] $p = 0.0029$; [2] $p = 0.0103$; [3] $p = 0.0190$; [4] $p = 0.0097$.

Table 2 Explorative analysis of plaque scores (mean±SD) for regions of interest

(n=35)		Experimental gingivitis phase		Treatment phase		
		Day 0	Day 21 (baseline gingivitis)	Week 1	Week 2	Week 4
All vestibular	PC 7000	0.83±0.48	3.17±0.39	0.84±0.52	0.59±0.46	0.79±0.48
	SE	0.82±0.51	3.14±0.40	1.06±0.60	0.82±0.45	0.98±0.53
		P=0.9478	P=0.9753	P=0.0166	P=0.0098	P=0.0295
All lingual	PC 7000	0.82±0.56	2.40±0.77	0.57±0.49	0.51±0.49	0.60±0.54
	SE	0.74±0.64	2.20±0.85	0.76±0.56	0.70±0.66	0.77±0.58
		P=0.4412	P=0.0453	P=0.0904	P=0.0462	P=0.0725
Mid-vestibular	PC 7000	0.36±0.48	3.15±0.46	0.54±0.64	0.35±0.46	0.46±0.55
	SE	0.39±0.59	3.06±0.52	0.58±0.62	0.36±0.42	0.47±0.50
		P=0.4620	P=0.1805	P=0.6258	P=0.7213	P=0.5222
Mid-lingual	PC 7000	0.79±0.65	2.31±0.85	0.49±0.56	0.46±0.53	0.56±0.61
	SE	0.72±0.73	2.11±0.87	0.77±0.66	0.66±0.74	0.68±0.70
		P=0.3472	P=0.0302	P=0.0460	P=0.1685	P=0.2932
Approximal vestibular	PC 7000	1.07±0.54	3.18±0.39	0.98±0.59	0.71±0.56	0.96±0.55
	SE	1.03±0.54	3.18±0.37	1.30±0.72	1.06±0.59	1.24±0.65
		P=0.5706	P=0.6742	P=0.0066	P=0.0057	P=0.0141
Approximal lingual	PC 7000	0.83±0.57	2.45±0.75	0.61±0.50	0.54±0.51	0.62±0.55
	SE	0.76±0.65	2.24±0.87	0.76±0.58	0.72±0.64	0.81±0.58
		P=0.4991	P=0.0724	P=0.1411	P=0.0473	P=0.0341

Comparison between toothbrushes by Wilcoxon test: original p-values.

Table 3 Explorative analysis of bleeding scores (mean±SD) for regions of interest

(n=35)		Experimental gingivitis phase		Treatment phase		
		Day 0	Day 21 (baseline gingivitis)	Week 1	Week 2	Week 4
All vestibular	PC 7000	0.71±0.35	1.81±0.32	1.32±0.37	1.15±0.44	0.98±0.42
	SE	0.82±0.33	1.86±0.29	1.56±0.32	1.44±0.29	1.29±0.34
		P=0.0008	P=0.0640	P=0.0005	P=0.0006	P=0.0021
All lingual	PC 7000	1.16±0.46	1.91±0.15	1.71±0.25	1.52±0.37	1.49±0.29
	SE	1.28±0.40	1.90±0.16	1.80±0.22	1.64±0.23	1.55±0.29
		P=0.1420	P=0.7002	P=0.0553	P=0.0248	P=0.3812
Mid-vestibular	PC 7000	0.69±0.41	1.76±0.37	1.23±0.42	1.10±0.46	1.02±0.41
	SE	0.90±0.46	1.83±0.36	1.44±0.45	1.26±0.35	1.18±0.37
		P=0.0187	P=0.1145	P=0.0062	P=0.0675	P=0.0712
Mid-lingual	PC 7000	1.26±0.53	1.91±0.17	1.68±0.31	1.54±0.42	1.60±0.29
	SE	1.35±0.50	1.86±0.21	1.79±0.27	1.66±0.26	1.59±0.33
		P=0.3180	P=0.0985	P=0.0622	P=0.2140	P=0.8548
Approximal vestibular	PC 7000	0.72±0.40	1.83±0.30	1.36±0.39	1.17±0.48	0.97±0.49
	SE	0.78±0.36	1.88±0.27	1.61±0.30	1.53±0.30	1.34±0.38
		P=0.4152	P=0.0540	P=0.0004	P=0.0002	P=0.0013
Approximal lingual	PC 7000	1.11±0.48	1.91±0.16	1.73±0.27	1.50±0.39	1.43±0.36
	SE	1.24±0.41	1.92±0.15	1.80±0.23	1.64±0.29	1.53±0.31
		P=0.1174	P=0.4729	P=0.1839	P=0.0221	P=0.1177

Comparison between toothbrushes by Wilcoxon test: original p-values.

Bleeding

During the experimental gingivitis phase (Day 0 to Day 21), the bleeding index increased noticeably and at Day 21 (baseline gingivitis) there was no significant difference between the two toothbrushes in the overall scores or measurements at individual sites (Tables 1 and 2). The bleeding index decreased considerably with both toothbrushes during the treatment phase. Comparison of the two toothbrushes showed that the

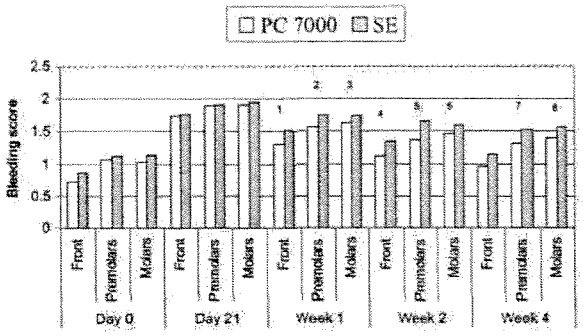


Figure 5. Bleeding score by tooth type. Wilcoxon test: $^{1}p = 0.0022$; $^{2}p = 0.0073$; $^{3}p = 0.0418$; $^{4}p = 0.0024$; $^{5}p = 0.0022$; $^{6}p = 0.0222$; $^{7}p = 0.0147$; $^{8}p = 0.0346$.

PC 7000 was significantly more effective than the SE toothbrush in reducing gingival bleeding throughout the treatment phase (Table 1). There was progressive improvement in bleeding with both toothbrushes, but greater reductions in bleeding scores were found with the PC 7000. After 4 weeks of use the mean bleeding scores decreased from 1.86 (Day 21) to 1.24 for the PC 7000 and from 1.88 (Day 21) to 1.42 for the SE. The Day 0 score was the only covariate significantly related to the dependent variables ($p < 0.0001$).

Explorative analysis of gingival bleeding by measurement site and tooth type showed the level of bleeding was lower with the PC 7000 at most measured sites and time points, including approximal sites, and for all tooth types (front, premolar and molar) (Table 3, Fig. 5).

Gingival abrasion

The overall gingival abrasion scores were comparable at Day 0. During the treatment phase, gingival abrasion scores were comparable with no significant difference between toothbrushes (except at Week 1 when fewer abrasions were evident with the SE) (Table 4). There were few medium sites and no large sites of gingival abrasion during the treatment phase with either toothbrush. No significant difference was found between toothbrushes in the gingival abrasion scores by gingival region, with most

Table 4 Gingival abrasion scores (mean±SD)

($n = 35$)		Experimental gingivitis phase Day 0	Treatment phase		
			Week 1	Week 2	Week 4
All lesions	PC 7000	1.34±2.05	1.43±1.91	0.86±1.29	1.54±2.23
	SE	1.26±1.77	0.71±1.47	1.54±2.34	1.71±2.72
		$P = 0.964$	$P = 0.044$	$P = 0.164$	$P = 0.383$
Small (≤2 mm)	PC 7000	1.09±1.67	1.29±1.82	0.83±1.29	1.51±2.23
	SE	1.11±1.60	0.69±1.37	1.46±2.20	1.57±2.30
		$P = 0.632$	$P = 0.072$	$P = 0.174$	$P = 0.419$
Medium (≥3 but <5 mm)	PC 7000	0.23±0.65	0.14±0.36	0.03±0.17	0.03±0.17
	SE	0.11±0.40	0.03±0.17	0.09±0.28	0.14±0.49
		$P = 0.157$	$P = 0.046$	$P = 0.317$	$P = 0.194$
Large (≥5 mm)	PC 7000	0.03±0.17	0.00±0.00	0.00±0.00	0.00±0.00
	SE	0.03±0.17	0.00±0.00	0.00±0.00	0.00±0.00
		$P = 1.000$	$P = 1.000$	$P = 1.000$	$P = 1.000$
Approximal	PC 7000	0.42±1.17	0.09±0.37	0.09±0.37	0.23±0.49
	SE	0.63±1.33	0.00±0.00	0.06±0.34	0.26±0.56
		$P = 0.124$	$P = 0.180$	$P = 0.785$	$P = 0.763$
Marginal	PC 7000	0.26±0.89	0.43±0.92	0.17±0.38	0.34±0.80
	SE	0.14±0.36	0.20±0.63	0.43±0.88	0.37±0.69
		$P = 0.739$	$P = 0.128$	$P = 0.204$	$P = 0.637$
Mid-gingival	PC 7000	0.66±1.24	0.91±1.62	0.60±1.24	0.97±2.09
	SE	0.49±1.20	0.51±1.17	1.06±1.71	1.09±2.52
		$P = 0.615$	$P = 0.158$	$P = 0.192$	$P = 0.426$
All vestibular	PC 7000	0.51±1.38	0.29±0.79	0.23±0.49	0.37±0.65
	SE	0.63±1.33	0.11±0.53	0.14±0.43	0.40±0.69
		$P = 0.331$	$P = 0.058$	$P = 0.477$	$P = 0.813$
All lingual	PC 7000	0.83±1.42	1.14±1.93	0.63±1.24	1.17±2.12
	SE	0.63±1.19	0.60±1.19	1.40±2.16	1.31±2.52
		$P = 0.532$	$P = 0.162$	$P = 0.051$	$P = 0.298$

Comparison between toothbrushes by Wilcoxon test: original p-values.

abrasions found in the mid-gingival and lingual aspects of the gingivae for both toothbrushes (Table 4).

Response to questionnaire

At the end of the last visit all subjects completed a questionnaire designed to evaluate their attitudes to both toothbrushes used in the study. Nearly all subjects stated that both toothbrushes were able to clean the teeth properly. When asked their opinion about which toothbrush was best in removing plaque, 24 (68.6%) subjects chose the PC 7000, 4 (11.4%) subjects chose the SE, and 7 (20.0%) subjects had no preference ($p < 0.001$). Average VAS scores in terms of pleasantness of use (range 0-10; 0 = unpleasant, 10 = very pleasant) were 6.6 (±2.25) for the SE and 7.3 (±2.04) for the PC 7000. In response to the question "Which brush would you take home if possible?", 66% of the subjects stated that they preferred the PC 7000, 31% preferred the SE and one subject (3%) had no preference.

Discussion

This study was designed to compare the effect on plaque and gingivitis of two novel power toothbrushes with different brush head designs and modes of operation. Professional instruction and training enables the user to achieve the maximum cleaning performance of electric toothbrushes[18], but these procedures are likely to benefit gingival condition. Consequently, the present study comprised a familiarisation phase and professional instruction for training purposes before an experimental gingivitis phase, during which an appropriate degree of gingivitis was established[17]. Participants in the study were derived from the general population, but smokers were excluded because an earlier study using bleeding on marginal probing as an indicator of gingivitis found that marginal bleeding caused by plaque accumulation was reduced in smokers[19]. With this study design, subjects who developed a sufficient level of gingivitis (bleeding on marginal probing ≥40%) entered into the treatment phase, and improvement in their gingival health was then observed after resuming tooth brushing. In the present study, the level of gingival bleeding on completion of the experimental gingivitis phase was approximately 1.9, which is comparable to values obtained in other studies using a similar model[17,28].

Data from this controlled, examiner-blind, split-mouth study demonstrate that both the PC 7000 toothbrush with its oscillating/rotating/pulsating action and the SE toothbrush with its high-frequency vibrating action are effective in plaque removal and improvement of experimentally induced gingivitis. However, despite a progressive decline in gingival bleeding during treatment, gingivitis was not completely resolved at the end of treatment with either toothbrush. With the PC 7000, overall plaque levels were lower than levels on Day 0 of the EIG phase from 1 week of treatment onwards, but with the SE the overall plaque levels were still higher than Day 0 levels after 4 weeks of treatment. Analyses of both plaque and bleeding treatment data took into account any imbalance in values obtained in EIG phase (by including Day 21 scores as covariates in the repeated measures ANOVA). Differences between toothbrushes were evident after 1 week of treatment onwards, with statistically significant advantages in both plaque removal and improvement of gingival condition in favour of the PC 7000.

Effective brushing remains the most obvious way of maintaining low levels of plaque and good gingival health. Gingivitis is known to be associated with the onset of periodontitis, and although the relationship between these two conditions may not be fully understood[1], the importance of maintaining good gingival health and preventing periodontitis is well recognised. Any advances to toothbrush design that can be shown to benefit gingival condition must therefore offer oral health care advantages to the user. Two previous studies have investigated the comparative effects on experimentally-induced gingivitis of earlier models of the Oral-B oscillating/rotating/pulsating toothbrush (3D and 3D Excel) and a high-frequency toothbrush (Sonicare Plus)[28,29]. Their results are in agreement with the findings of the present study, where the Oral-B three-dimensional action demonstrated significantly greater plaque removal efficacy and ability to improve gingival condition than the Sonicare toothbrush. Most notably, however, the present study specifically scored both plaque and bleeding indices at varying sites within the mouth in order to differentiate more closely between the cleaning profiles of the two types of toothbrush. Interestingly, the benefits of the PC 7000 over the SE in terms of plaque reduction and improved gingival health were most apparent at approximal sites, where the initiation and progression of gingivitis is most prevalent[11,12]. Furthermore, reduction in plaque and gingival bleeding by tooth type revealed that significant advantages in favour of the PC 7000 occurred on front, premolar and molar teeth.

Excessive brushing force can traumatise oral soft and hard tissue[30]. In this study, evidence of any trauma on the gingivae after brushing was identified by use of a disclosing agent to stain disruption of oral tissue, a method previously shown to highlight minor abrasions that would otherwise be difficult to detect[26]. The potential of the PC 7000 and SE to cause gingival abrasion was comparable, with the vast majority of abrasion sites found as minor (≤2 mm), few as medium (≥3 but <5 mm) and none as large (≥5 mm). With regard to the location of abrasion sites, for both toothbrushes most abrasions were found in the mid-gingival and lingual aspects of the gingivae. Other studies investigating the potential of the Oral-B 3D Plaque Remover to cause gingival abrasion found no greater incidence of abrasions compared to manual tooth brushing or an earlier oscillating/rotating model (D9)[23,31].

The advantage in terms of plaque removal associated with the use of an electric toothbrush is dependent on good compliance and continued use in the long term. Any dissatisfaction is likely to lead to discontinuation and loss of potential advantages. In this study, the majority of the subjects preferred the PC 7000 over the SE and selected the PC 7000 as the toothbrush they would choose to take

home if possible. These findings may have implications for patient compliance during long-term use.

Conclusion

The oscillating/rotating/pulsating toothbrush was significantly more effective in plaque removal and improvement of experimentally induced gingivitis than the high-frequency vibrating toothbrush, with no greater potential for causing gingival abrasion.

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